510(k) Summary
for the Sorin Group Deutschland GmbH
Sorin Centrifugal Pump (CP5)

SEP 2 0 2011

(21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

K112225

1. SPONSOR/APPLICANT

Sorin Group Deutschland GmbH
Lindberghstrasse 25
D-80939 Munich
Germany
Contact Person: Renate Goebert
Telephone: 011 +49 (0)89 323 01 153

Date Prepared: September 1, 2011

2. DEVICE NAME

Proprietary Name: Sorin Centrifugal Pump (CP5)
Common/Usual Name: Cardiopulmonary bypass centrifugal pump
Classification Name: Cardiopulmonary bypass speed control device (*21 CFR 870.4380; Product Code: DWA*)

3. PREDICATE DEVICE/S

- Stöckert Centrifugal Pump System Plus for the S5/C5 System (K103468)
- Pulse Mode Control for the S5 System (K071318)

4. DEVICE DESCRIPTION

- **Physical description**

  The Sorin CP5 is intended for use as a component part of or optional accessory for the Sorin heart lung machine consoles and with the Stöckert Air Purge (APC) System. The Sorin CP5 consists of the drive unit, a mounting receptacle for the pump head, a retaining key, splash protection, and a 3-joint mast holder with fast clamp connector. It integrates the functional capabilities of the SCP, the SCP Plus, and the Sorin Pulse Mode Control within a single device.

- **How the device functions**

  The Sorin CP5 consists of hardware, firmware, and electronics that are used to drive the centrifugal pump for surgical procedures requiring cardiopulmonary bypass for typical durations of six (6) hours or less. The SCP drive unit uses magnetic coupling with the disposable centrifugal pump.

- **Scientific concepts that form the basis for the device**

  The Sorin CP5 with the loaded centrifugal pump recirculates the contents of the extracorporeal circuit during cardiopulmonary bypass.

- **Significant physical and performance characteristics of the device, such as device design, material used, and physical properties**

  The design, materials, and physical properties of the CP5 are essentially unchanged from that of the parent/predicate devices already reviewed and cleared by the FDA.

5. INTENDED USE/INDICATION FOR USE

The Sorin Centrifugal Pump (CP5) is a cardiopulmonary bypass speed control device indicated for use exclusively with the Sorin Revolution®, for speed-controlled pumping through the cardiopulmonary bypass circuit for typical durations of six hours or less.

The CP5 has been qualified only for typical durations of six hours or less, appropriate to cardiopulmonary bypass procedures and has not been qualified through in vitro, in vivo, or clinical studies, for long term use as a bridge to transplant, pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The technological characteristics of the Sorin CP5 described in this Special 510(k): Device Modification are substantially equivalent to cited parent/predicate devices previously reviewed and cleared by the FDA. Characteristics unchanged from the parent/predicate devices include the following: firmware control; magnetic coupling with disposable pump head; speed control with shaft encoder; data transfer via CAN bus; mast mounted drive unit with fast clamp connector; hosing materials; motor; DC power supply from HLM; microcontroller; programming language; and tools for code implementation. Minor differences include the following: panel hosing and mounting; control keys; data connection to drive unit; use of an OTS operating system and user

interface; complier; CAN bus identifiers and identification method; and addition of ramp down function and inlet pressure measurement.

7. **SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE**

No comparative nonclinical testing served as the basis for substantial equivalence. Testing consisted of integration testing of hardware and firmware, functional acceptance testing, safety testing (IEC 60601-1 including deviations for the US and Canada), EMI/EMC testing (IEC 60601-1-2), and validation testing (simulated use and in use).

8. **SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE**

No clinical testing served as the basis for substantial equivalence.

9. **SUMMARY OF OTHER INFORMATION**

No "other information" was included in this 510(k).

10. **CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS**

Testing of the Sorin Centrifugal Pump (CP5) demonstrates that the CP5 fulfills prospectively defined performance criteria and meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –W066-G609
Silver Spring, MD 20993-0002

Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

SEP 20 2011

Re: K112225
Trade/Device Name: Sorin Centrifugal Pump (CP5)
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary bypass pump speed control
Regulatory Class: II
Product Code: DWA
Dated: September 1, 2011
Received: September 2, 2011

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112225

Device Name: Sorin Centrifugal Pump (CP5)

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112225